

United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS COMMITTEE ON THE JUDICIARY SELECT COMMITTEE ON INTELLIGENCE COMMITTEE ON THE BUDGET

May 7, 2020

The Honorable Peter Gaynor Administrator Federal Emergency Management Agency 500 C Street SW Washington, DC 20472 The Honorable Alex Azar Secretary Department of Health and Human Services 200 Independence Ave SW Washington, DC 20201

Dear Administrator Gaynor and Secretary Azar:

I am writing to request more transparency around the federal government's distribution of remdesivir to hospitals and health systems. I urge the Federal Emergency Management Agency (FEMA) and the Department of Health and Human Services (HHS) to ensure equitable distribution of the drug across states and regions, including to communities with high levels of racial and ethnic disparities in COVID-19 cases and deaths.

As you know, the Food and Drug Administration (FDA) granted an emergency use authorization (EUA) for remdesivir, an investigational antiviral treatment, on May 1, 2020. This was based on preliminary data from a National Institute of Allergy and Infectious Diseases study showing patients who received remdesivir recovered faster than similar patients who received a placebo. Gilead Sciences has donated 1.5 million doses of remdesivir – their existing supply of the product – to the federal government. Assuming a 10-day course of treatment, this donation is likely enough for 140,000 patients.

It is crucial that distribution of this drug and any subsequent authorized treatments optimizes public health. Given the staggering racial and ethnic disparities that have emerged during this pandemic, an equitable distribution of remdesivir is necessary to address and reduce the adverse COVID-19 health outcomes in the African American, Latinx, American Indian, Alaska Native, and Pacific Islander communities.

The American people deserve transparency about the methodology and timeline of distribution of remdesivir. Public reporting suggests FEMA and HHS are in charge of distributing the existing doses of remdesivir. As of May 6, HHS reportedly approved 25 hospitals to receive remdesivir under the EUA. At this time, I am unaware of any California hospitals – including those in current hot spots – that have received a remdesivir allocation from the federal government despite some even participating in clinical

¹ https://www.fda.gov/media/137564/download

² https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19

 $[\]frac{3 \text{ https://www.gilead.com/news-and-press/press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19}{\text{ press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19}{\text{ press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19}{\text{ press-room/press-room/press-releases/2020/5/gileads-investigational-antiviral-remdesivir-receives-us-food-and-drug-administration-emergency-use-authorization-for-the-treatment-of-covid19}{\text{ press-room/press-room/press-releases/2020/5/gileads-investigation-for-the-treatment-of-covid19}}{\text{ press-room/pr$

⁴ Id.

⁵ https://www.politico.com/news/2020/05/06/remdesivir-helps-coronavirus-patients-but-at-what-cost-240230

⁶ https://www.statnews.com/2020/05/06/doctors-lambaste-federal-process-for-distributing-covid-19-drug-remdesivir/

trials on the drug. Additionally, the Howard University Hospital, the only Historically Black College and University (HBCU)-owned hospital, which plays a critical role in serving African Americans, one of the communities that has been hit the hardest by COVID-19, also did not receive any remdesivir in the initial distribution. In fact, no hospital in the District of Columbia received doses, a city where African Americans make up 46% of the population but 79% of the COVID-19-related deaths. The fact that many of the hospitals and areas with high rates of COVID-19 cases and deaths were left out of the initial distribution raises significant questions about FEMA and HHS' decision making.

I have previously requested information on how FEMA and HHS are making critical decisions and addressing racial and ethnic disparities. On April 3, I sent a letter to FEMA and HHS requesting detailed information on how scarce resources were being distributed. On April 24, I sent a letter to FEMA requesting information on how the agency was addressing the racial and ethnic disparities in COVID-19 cases and deaths. I have not received an answer to either letter and the current reporting regarding the distribution of remdesivir is cause for continued concern.

I request answers to the following questions by next Friday, May 15, 2020.

- 1. To date, how many hospitals and/or health systems have received allocations of remdesivir from the federal government?
- 2. What criteria or methodology did FEMA and HHS use to select which hospitals and/or health systems received remdesivir?
 - a. Did you consider hospitals and/or health systems serving COVID-19 hot spots?
 - b. Did you consider hospitals and/or health systems serving disproportionately impacted communities of color, such as public hospitals and hospitals owned or affiliated with HBCUs?
- 3. What criteria or methodology does FEMA and HHS plan to use to allocate the remaining doses of remdesivir?
- 4. When do FEMA and HHS plan to announce further allocations of remdesivir?
- 5. Given the current number of available doses, how many additional hospitals and/or health systems do FEMA and HHS anticipate will receive remdesivir allocations?
- 6. How do FEMA and HHS plan to ensure an equitable distribution of remdesivir to hospitals and health systems across regions and states?
- 7. How do FEMA and HHS plan to ensure equitable distribution of remdesivir for racial and ethnic groups that have been disproportionately affected by COVID-19?
- 8. How are FEMA and HHS addressing the needs of public hospitals, hospitals owned or affiliated with HBCUs, and other hospitals and/or health systems serving disproportionately impacted communities of color?

⁷ https://www.census.gov/quickfacts/DC; https://coronavirus.dc.gov/page/coronavirus-data

9. As clinical trials continue across the nation and the world, how do FEMA and HHS plan to ensure equitable distribution of future COVID-19 treatments and vaccines?

Thank you for your attention to this urgent issue.

Sincerely,

KAMALA D. HARRIS

U.S. Senator